K051257

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CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL ROAD, BRANFORD, CONNECTICUT 06405

203-488-6056
(FAX) 203-488-9438

DEC 2 2 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

Address: 44 East Industrial Rd. Branford CT. 06405 USA

Contact: Ron Jeffrey – Director, Regulatory Affairs
Phone - (203) 488-6056 Fax – (203) 488-9438
Email – rjeffrey@casmed.com

Prepared: May 9, 2005

Trade Name: Adult Cerebral Oximeter Monitor

Common Name: Model 2040 Monitor

Classification Name: Cerebral Oximeter (870.2700)

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EQUIVALENCE (Predicate Device)

The Adult Cerebral Oximeter Monitor, Model 2040 is equivalent to the following devices:

- Somanetics Invos® 5100 / 3100A Cerebral Oximeter (K001842 / K960614);
- Spectros T-Stat™ 303 Microvascular Tissue Oximeter (K040684);
- Hitachi Medical ETG-4000 / 1000 Optical Topography System (K042501 / 011320).

DESCRIPTION

The Adult Cerebral Oximeter, model 2040 measures brain oxygenation allowing the clinician to accurately determine absolute levels of tissue and venous oxygenation in the brain. This measurement can be of significant value in numerous acute care (OR, ICU, ER) situations, providing health care professionals with information to guard against neurological injuries due to compromised brain oxygenation, which can occur during many surgical and clinical situations.

The 2040 Cerebral Oximeter consists of an optical transducer containing a laser light source and photodiode detectors, and a graphic display monitor with user interface. The non-invasive, reflection mode, optical transducer is placed on the forehead of the subject via a disposable probe attachment to determine cerebral oxygenation. The 2040 Cerebral Oximeter will be safe to use, since it is designed to operate as a Class I laser product, the safest FDA laser classification. Additional safety features include a laser interlock system designed to prevent laser operation in case the optical transducer is not securely attached to the subject. A patent-protected algorithm optimizes accuracy of the device in measurements of absolute brain tissue oxygen saturation and, in conjunction with pulse oximetry, in providing absolute readings of brain venous oxygen saturation..

Adult Cerebral Oximeter Intended Use

The non-invasive Adult Cerebral Oximeter Model 2040 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. The Cerebral Oximeter Monitor System should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the Cerebral Oximeter Monitoring System has not been demonstrated in disease states.

Device Technological Characteristics Comparing Device to Predicates

The Adult Cerebral Oximeter, Model 2040 compares substantially to one or more of the predicates cited in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All monitors use light to probe a cross-section of the microvasculature of tissue (mixed bed of arterioles, capillaries and venuoles). The 2040 and predicates analyze light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region. All calculate tissue oxygen saturation (%St02), a value reflecting percentage of oxygenated hemoglobin in the sampled mircovasculature of tissue.

Nonclinical Performance Testing to Show Substantial Equivalence

The Adult Cerebral Oximeter, Model 2040 will be tested in accordance with the following standards as per CAS Product Performance Specifications prior to release to market. The following non-clinical tests will be performed:

- UL60601-1 (w/ CSA 22.2 No. 60601-1) Safety testing for use of the UL Classified mark;
- IEC60601-1 Safety of Medical Electrical Equipment;
- EN60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- EN 865 Pulse Oximeters (CAS VP/VR 050022) – Particular Requirements (as applicable);
- Testing specified in the Reviewer Guidance for Premarket Notification Submissions – (CAS 21-07-0076)
- VP/VR 050012 – System Validation Plan
- VP/VR 050013 – System IPX1 Verification Plan
- VP/VR 050014 – Hardware Verification Plan

Clinical Testing to Show Substantial Equivalence

Clinical data on adult subjects was collected at the Duke University Medical Center in Durham, North Carolina. In this study, healthy adult volunteers were subjects for comparison using an internal jugular bulb catheter on the subject's right side and a radial arterial line on the left. Two sensors from the cerebral oximeter model 2040 were placed on the patient's forehead, on the right and left sides respectively. Hypoxic mixtures of gas were delivered and data was collected a different periods of ascending and descending concentrations in 5 minute intervals. At set points, blood samples were drawn simultaneously from the jugular bulb and the radial arterial catheters and analysis for oxygen tension was performed using a co-oximeter. The patient was monitored and protocol stopped if Sp02 values from a pulse oximeter reached <70%.

Conclusions Drawn from Clinical and Nonclinical Testing

The model 2040 St02 showed a strong correlation with the reference St02 over the spectrum of Sp02 values between 70 and 100%. The bias and precision (1 standard deviation) for the model 2040 St02 compared to reference St02 derived from co-oximetry of arterial (Sa02) and jugular bulb (Sjb02) blood samples was 0.43 ± 3.78, based on the following expression:

$$Reference\ St02\% = Sa02 \times 0.3 + Sjb02 \times 0.7$$

The cerebral oximeter St02 value represents oxygen saturation in the brain tissue microvasculature containing venous and arterial blood volume at a ratio of 70:30. The model 2040 Sv02 showed a strong correlation with the reference SjbO2 over the spectrum of Sp02 values between 70 and 100%. The bias and precision for the model 2040 Sv02 compared to reference SjbO2, derived from co-oximetry of the jugular bulb blood samples was 0.63 ± 5.38. Sv02 was determined from the following expression:

$$Sv02 = (St02 - Sp02 \times 0.3) / 0.7$$

In the above expression, Sp02 is arterial oxygen saturation from a pulse oximeter and St02 is determined by the cerebral oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Mr. Ron Jeffrey
Director, Regulatory Affairs
CAS Medical Systems, Inc.
44 East Industrial Road
Branford, Connecticut 06405

Re: K051257
Trade/Device Name: Adult Cerebral Oximeter Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 2, 2005
Received: December 5, 2005

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Barbara Melkerson
for

Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051257

Device Name: Adult Cerebral Oximeter, Model 2040

Indications for Use: The non-invasive Adult Cerebral Oximeter Model 2040 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. The Cerebral Oximeter Monitor System should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the Cerebral Oximeter Monitoring System has not been demonstrated in disease states.

Prescription Use ✓ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brennan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051257